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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,069	11/09/2000	Joseph R. Codispoti	MCP-264	3552

7590 02/27/2002

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[REDACTED] EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
1614	7

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/709,069	CODISPOTI, JOSEPH R.	
	Examiner	Art Unit	
	Donna A. Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-26 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 475

- 4) Interview Summary (PTO-413) Paper No(s). ____ .
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

Claims 1-26 are presented for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-26 are rejected under 35 U.S.C. 102(f) as being anticipated by Furey et al. (AO).

This has been made under 102(f) because it is not completely clear what the publication day of the reference is. Furey et al. (V) teach 400-600 mg of ibuprofen liquigels effectively relieving migraine pain, reduced ancillary migraine symptoms and improved migrainer quality-of-life. The preferred dose was 400 mg (see abstract). Furey et al. (V) further teach that 400 mg and 600 mg were both superior to placebo with no nausea, **photophobia** and **phonophobia** over 4 hours. (See abstract).

Regarding the isomers of ibuprofen, in general, stereoisomers/optical isomers are obvious from racemic mixtures. As legal authority the examiner cites *In re Adamson and Duffin*, 125 U.S.P.Q. 233. The case sets forth the requirements of patentability with regard to stereoisomers as follows:

- 1) The existence of a racemate is, in and of itself, sufficient to render obvious any individual stereoisomers contained within; no express suggestion of isomer separation is needed. See the first paragraph on page 235.

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2) One skilled in the art expects that individual stereoisomers will differ significantly in physiological/pharmacological activity and toxicity, because living systems are chiral and thus preferentially process stereochemical configurations over others. See page 234, the third full paragraph and page 235, the fifth full paragraph on the page.

S (+)-ibuprofen is known from the recitation of oral formulations of S (+)-ibuprofen of EP 0 753 296 A2; it is taught to be useful for headaches (Page 2, lines 49-52). Consonant with the reasoning of *Adamson*, the existence of that racemate renders obvious any individual stereoisomers contained within, i.e. the R and S enantiomers recited instantly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diener et al. (AG) in view of Mauskop (AC).

The claims are drawn to a method of mitigating or treating photophobia and phonophobia associated with a migraine by administering ibuprofen with dependent claims drawn to isomers and further comprising *inter alia* caffeine.

Diener et al (AG) teach a guide to the management and prevention of migraine headaches. Aspirin, **ibuprofen** and paracetamol (acetaminophen) are noted as first-choice analgesics for mild to moderate migraine attacks (page 813, column 2, lines 3-5). Diener et al (U) further teach that migraine is a paroxysmal disorder with attacks of headache, nausea, vomiting, **photo** and **phonophobia** and malaise (see abstract).

It differs from the instant claims in that it does not explicitly teach targeting photo and phonophobia and it does not teach the isomers.

Mauskop (A) teaches the administration of an analgesic composition comprising ibuprofen and magnesium and caffeine (column 2, line 55 to column 3, line 18 and column 7, example 4) and teaches that photo and phonophobia are symptoms normally targeted during migraine treatment (see abstract). It differs from the instant claims in that it requires a magnesium component.

Regarding the isomers of ibuprofen, in general, stereoisomers/optical isomers are obvious from racemic mixtures. As legal authority the examiner cites *In re Adamson and Duffin*, 125 U.S.P.Q. 233. The case sets forth the requirements of patentability with regard to stereoisomers as follows:

- 1) The existence of a racemate is, in and of itself, sufficient to render obvious any individual stereoisomers contained within; no express suggestion of isomer separation is needed. See the first paragraph on page 235.

2) One skilled in the art expects that individual stereoisomers will differ significantly in physiological/pharmacological activity and toxicity, because living systems are chiral and thus preferentially process stereochemical configurations over others. See page 234, the third full paragraph and page 235, the fifth full paragraph on the page.

S (+)-ibuprofen is known from the recitation of oral formulations of S (+)-ibuprofen of EP 0 753 296 A2; it is taught to be useful for headaches (Page 2, lines 49-52). Consistent with the reasoning of *Adamson*, the existence of that racemate renders obvious any individual stereoisomers contained within, i.e. the R and S enantiomers recited instantly.

It would have been obvious to have targeted photo and phonophobia during treatment with ibuprofen disclosed by references (AG) and, since this is well known as taught by reference (AC).

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna A. Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on 6:30 A.M. - 3 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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305-3230 for regular communications and (703) 308-7921 for After Final
communications.

Any inquiry of a general nature or relating to the status of this application or
proceeding should be directed to the receptionist whose telephone number is (703) 308-
0193.

dj

February 18, 2002

NO

NESTORIK KRASS
PRIMARY EXAMINER
GROUP 16

